REMARKS

This Amendment, filed in conjunction with a Request for Continued Examination ("RCE"), responds to the final Office Action mailed 24 July 2007. The filing of this Amendment and RCE is permissible under 37 C.F.R. § 1.114. *See* M.P.E.P. § 706.07(h).

Claims 35, 37, 44, 49, 55, 63, 67, and 71 have been amended and claims 50, 74, and 75 have been canceled. Accordingly, Claims 35-39, 41-49, 51-73, 76, and 77 are presently pending in this application, each of which Applicant believes is in immediate condition for allowance. Applicant respectfully requests reexamination and reconsideration in light of the following remarks.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks primarily focus on the rejections applied to the independent claims (*i.e.*, claims 35, 37, 44, 49, 55, 63, 67, and 71) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 35, 37, 38, 41-49, 51-55, 57-62, 71, and 73-77 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,662,681 to Nash et al. ("Nash"). The Examiner also rejected claims 37 and 39 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,814,073 to Bonutti et al. ("Bonutti"). Additionally, the Examiner rejected claims 67-70 under 35 U.S.C. § 102(b) as allegedly being

anticipated by U.S. Patent No. 5,282,827 to Kensey et al. ("Kensey"). Applicant respectfully traverses this rejection.

A. Independent Claim 35

Independent claim 35 of the present application recites, *inter alia*, "a multi-level nest disposed in the carrier tube, the filament also connected to a sealing plug located proximal of the anchor for disposition and anchoring about the tissue puncture, wherein the multi-level nest comprises: a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the carrier tube."

Nash, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 35. For example, at the very least, Nash fails to disclose, teach, or even suggest "a multi-level nest [comprising] a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the carrier tube" Instead, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102" *See, e.g.*, col. 4, lines 43-45 and FIG. 1 of Nash.

B. Independent Claim 37

Independent claim 37 of the present application recites, *inter alia*, "a gap that extends between a carrier tube of the tissue puncture sealing device and the anchor in a direction that is transverse to the carrier tube, the gap being created by a multi-level nest in the carrier tube or an indentation in the anchor, wherein the multi-level nest comprises: a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the carrier tube."

Nash and Bonutti, however, each clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 35. For example, at the very least, Nash fails to disclose, teach, or even suggest "a multi-level nest in the carrier tube" comprising "a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the carrier tube" Instead, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102." *See, e.g.*, col. 4, lines 43-45 and FIG. 1 of Nash.

Additionally, Bonutti, at the very least, fails to disclose, teach, or even suggest ""a multi-level nest in the carrier tube" comprising "a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the carrier tube." In other words, Bonutti fails to teach that a portion of tubular inner member 54 is spaced from suture anchor 22 in a direction radially inward relative to inner member 54. *See, e.g.*, col. 6, lines 48-50 of Bonutti ("[t]he tubular inner member 54 is manually pressed against the annular trailing end portion 50 of the suture anchor 22."); *see also* FIGS. 1 and 10.

Bonutti also fails to disclose, teach, or suggest "a gap that extends between a carrier tube of the tissue puncture sealing device and the anchor in a direction that is transverse to the carrier tube." In other words, Bonutti fails to teach that a portion of tubular inner member 54 is spaced from suture anchor 22 in a direction that is transverse to inner member 54. *See, e.g.*, col. 6, lines 48-50 of Bonutti ("[t]he tubular inner member 54 is manually pressed against the annular trailing end portion 50 of the suture anchor 22."); *see also* FIGS. 1 and 10.

C. Independent Claim 44

Independent claim 44 of the present application recites, *inter alia*, a "carrier tube including an outer surface, the outer surface including a first surface portion that is in contact

with the anchor and a second surface portion that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion."

Nash, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 44. For example, at the very least, Nash fails to disclose, teach, or even suggest a "carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a second surface portion that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion." Instead, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102." *See, e.g.,* col. 4, lines 43-45 and FIG. 1 of Nash.

D. Independent Claim 49

Independent claim 49 of the present application recites, *inter alia,* a "carrier tube being positioned so that a gap is formed between the anchor and the carrier tube in a direction that is transverse to the carrier tube; moving a tip of an insertion sheath into the gap formed between the anchor and the carrier tube to deploy the anchor."

Nash, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 49. For example, at the very least, Nash fails to disclose, teach, or even suggest "moving a tip of an insertion sheath into the gap formed between the anchor and the carrier tube to deploy the anchor." Instead, Nash merely teaches that anchor member 32 and tubular carrier 102 are disposed within bypass tube 104 prior to deployment, and that anchor member 32 is deployed by being pushed out of bypass tube 104 while bypass tube 104 remains in place. *See, e.g.,* col. 4, lines 43-45 of Nash ("the anchor member 32 is disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102.")

(emphasis added); *see also* col. 6, lines 62-66 ("The deployment instrument is then pushed fully down the introducer sheath, whereupon the bypass tube remains in the sheath and the anchor member 32 is deposited in the artery 26 beyond the distal end of the introducer sheath."); *see also* FIG. 1.

E. Independent Claim 55

Independent claim 55 of the present application recites, *inter alia*, a "carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a recess positioned adjacent to the anchor, the recess extending radially further into the carrier tube than the first surface portion."

Nash, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 55. For example, at the very least, Nash fails to disclose, teach, or even suggest "carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a recess positioned adjacent to the anchor, the recess extending radially further into the carrier tube than the first surface portion." Rather, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102." *See, e.g.*, col. 4, lines 43-45 and FIG. 1 of Nash.

F. Independent Claim 67

Independent claim 67 of the present application recites, *inter alia*, a "an anchor, the anchor including an indentation forming a gap between the anchor and the carrier tube; positioning a tip of an insertion sheath in the indentation."

Kensey, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 67. For example, at the very least, Kensey fails to disclose, teach,

or even suggest "positioning a tip of an insertion sheath in the indentation." Instead, Kensey merely discloses that an "instrument is [] pushed fully down the introducer sheath," after which time "the anchor member 32 will be located in the artery 26 beyond the distal end of the introducer sheath." *See, e.g.*, col. 11, line 63 to col. 12, line 2 and FIGS. 16-18 of Kensey; *see also* FIGS. 34 and 35.

G. Independent Claim 71

Independent claim 71 of the present application recites, *inter alia*, a "carrier tube including a recess positioned adjacent to one end of the anchor, wherein the recess extends between the carrier tube and the anchor to form a gap between the carrier tube and the anchor in a direction that is transverse to the carrier tube; positioning a tip of an insertion sheath in the recess between the carrier tube and the anchor."

Nash, however, clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 71. For example, at the very least, Nash fails to disclose, teach, or even suggest "positioning a tip of an insertion sheath in the recess between the carrier tube and the anchor." Rather, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102." *See, e.g.*, col. 4, lines 43-45 and FIG. 1 of Nash.

H. Dependent Claims

Aside from the novel limitations recited therein, claims 38, 39, 41-43, 45-49, 51-54, 57-62, 68-70, 73, 76, and 77 are also allowable at least by virtue of their dependency upon allowable base claims 35, 37, 44, 49, 55, 67, and 71. Applicant respectfully requests, therefore, that the rejection of claims 1-8 and 10-34 under 35 U.S.C. § 102(e) be withdrawn, and these claims be allowed.

Claim Rejections – 35 U.S.C. § 103

In the Action, the Examiner rejected claims 36, 50, 56, 63-66, and 72 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nash in view of Bonutti. Applicant respectfully traverses this rejection.

A. Independent Claim 63

In order to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, a reference (or references when combined) must teach or suggest each and every claim element. *See, e.g., In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *accord.* MPEP 2143.03. Independent claim 63 of the present application recites, *inter alia*, "positioning a tip of an insertion sheath between the anchor and the carrier tube in a direction that is transverse to the carrier tube; moving a tip of the insertion sheath underneath the anchor to deploy the anchor."

Nash clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 63. For example, at the very least, Nash fails to disclose, teach, or even suggest "positioning a tip of an insertion sheath between the anchor and the carrier tube in a direction that is transverse to the carrier tube." Nash also fails to disclose, teach, or suggest "moving a tip of the insertion sheath underneath the anchor to deploy the anchor." Rather, Nash merely discloses an "anchor member 32 [] disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis of the carrier tube 102." *See, e.g.,* col. 4, lines 43-45 and FIG. 1 of Nash.

Additionally, Bonutti also clearly fails to disclose, teach, or suggest each and every limitation recited in independent claim 63. For example, at the very least, Bonutti fails to disclose, teach, or even suggest "positioning a tip of an insertion sheath between the anchor and the carrier tube in a direction that is transverse to the carrier tube." Also, Bonutti fails to

disclose, teach, or suggest "moving a tip of the insertion sheath underneath the anchor to deploy the anchor."

The Examiner argues on page 9 of the Office Action that Bonutti teaches that "an introducer sheath (30) may have a resilient tips (see column, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment."

However, Bonutti does not disclose, teach, or even suggest that the introducer sheath 30 has resilient tips that move "to closed (upon passage of the anchor through the tip of the introducer sheath) positions" as argued by the Examiner, but rather, Bonutti teaches the exact opposite. Bonutti states:

> "Once the suture anchor 22 has been moved into the body tissue 24, the inserter assembly 20 is withdrawn from the body tissue. Since the tubular inner member 54 has moved into the open leading end portion 2 of the tubular outer member 30, the leading end portion of the tubular outer member is maintained in the open condition by the presence of the tubular outer member 54. Thus, the inner side surface 140 of the segments 88-94 are pressed firmly against the cylindrical outer side surface 110 of the tubular inner member by the natural resilience of the segments. This results in the leading end portion 62 of the tubular outer member 30 **being maintained in the open condition** as the inserter assembly is withdrawn from the body tissue."

Col. 7, lines 47-54 of Bonutti (emphasis added). In other words, Bonutti teaches that leading end portion 62 is pushed open by the suture anchor 22 and is maintained in an open condition by the tubular inner member during and after the anchor moving suture anchor 22 into body tissue 24. *See, e.g.*, FIGS. 1 and 4 of Bonutti.

Accordingly, because Nash and Bonutti, either alone or in combination, fail to disclose, teach or suggest each and every limitation of independent claim 63, a *prima facie* case of

obviousness has not been established. *See, e.g., In re Royka*, 490 F.2d 981, 985 (CCPA 1974) (holding that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art); *accord.* MPEP § 2143.03 ("To establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.") (emphasis added). Applicant therefore respectfully requests withdrawal of this rejection.

H. Dependent Claims

Moreover, aside from the novel limitations recited therein, claims 36, 56, 64-66, and 72 are also allowable at least by virtue of their dependency upon allowable base claims 35, 55, 63, and 71. Applicant respectfully request, therefore, that the rejection of claims 36, 56, 64-66, and 72 under 35 U.S.C. § 103(a) be withdrawn, and these claims be allowed.

Conclusion

Applicant respectfully submits that the present application is in condition for allowance. Applicant requests reconsideration and allowance of the pending claims. Applicant invites the Examiner to contact the undersigned by telephone to expedite prosecution of the present application if there remain any unresolved issues.

Respectfully submitted,

Date 26 NOVEMBER 2007 By _____

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